The *JID* Opens Its Doors to High-Quality Randomized Controlled Clinical Trials

The *Journal of Investigative Dermatology* (*JID*) may not strike you as the most obvious place to submit the results of your randomized controlled clinical trial (RCT) for publication. Over the last 6 years, for instance, the *JID* has published only 13 full RCTs compared with 151 in the *British Journal of Dermatology* (Table 1). Such a paucity of RCTs in the *JID* is largely due to a low number of submissions — possibly fuelled by the misguided perception that the *JID* is only concerned with basic science. People just do not think of the *JID* when considering where to publish their trial.

But things are about to change. Over the past few years, the *JID* has strived to increase its clinical relevance and scope of publications by including high-quality studies on epidemiology, health-services research, and clinical dermatology. The interest in clinical trials in the *JID* has existed from our very inception in 1938. The second issue of this journal reported an extensive study of the effect of a gold compound, ammonium succinimido-aurate, in 86 patients with lupus erythematosus (Obermayer and Becker, 1938). Perceptive presidential addresses by Donald Pillsbury on controls in clinical investigations (Pillsbury *et al.*, 1950) and Harvey Blank on bringing science to clinical trials (Blank, 1961) addressed many issues still relevant today. These two papers gathering dust in papyro-space are appended, allowing easy review of the prescient remarks of these individuals (see Supplementary Articles S1 and S2). We realize that the RCT is the current gold standard, but one should not be surprised when it is superseded and replaced by new ways of clinical study and analysis. Because many of those reading the *JID* today are practicing clinicians with an interest in evidence-based dermatology who wish to base their treatment choices on reliable evidence from randomized controlled trials, the *JID* wishes to actively encourage trialists to submit their findings to the journal. With its high impact factor and wide circulation through Nature Publishing Group, publishing a clinical trial in the *JID* means that it will reach a wide and influential audience. So, now that we have declared an interest in publishing RCTs, the question arises: what sort of trials? The short answer is that we would like the good ones — trials that are both important and well reported. These terms require elaboration in order to guide potential authors.

By "important" we mean trials that could have a significant impact for clinicians and their patients. Non-pharmacological interventions can be particularly interesting (Staab *et al.*, 2006), and trials of existing treatments that have never been tested in RCTs can also be worthwhile (Heydendael *et al.*, 2003). Trials that reveal novel insights into disease mechanisms and industry-independent studies that compare new pharmacological agents against existing active therapies are also encouraged (Wolkenstein *et al.*, 1998; Ozolins *et al.*, 2004). We are less interested in trials that investigate small incremental differences in "me too" drugs, dose-finding studies, and trials of new pharmacological agents that compare their drugs against placebo only. By "well reported," we mean that the trial must include the sort of essential data that will allow a reader to quickly appraise the quality of the study. Like other top journals, the *JID* has adopted the CONSORT statement (www.consort-statement.org) in its instructions to authors to ensure that all the essential components of the trial are described (Moher *et al.*, 2001). Yet another checklist might sound a little tedious for those submitting papers, but the general standard of reporting clinical trials in dermatology has not been good in the past (Adetugbo and Williams, 2000). Information such as a participant flow diagram indicating how many participants were initially randomized and how many were eventually accounted for in the analysis is considered essential in order to understand how the conclusions of a trial relate to those who took part in it (Egger *et al.*, 2001). A clear description of how the randomization sequence was generated and subsequently concealed from those recruiting study participants has been shown to be a key indicator of study quality (Hewitt *et al.*, 2005), yet

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Table 1 | Number of full randomized controlled trial reports in four leading dermatology journals from 2000 to 2005, identified by hand-searching

Journal	2000	2001	2002	2003	2004	2005	Total
Arch Dermatol	9	8	15	17	20	14	83
Br J Dermatol	23	27	29	21	26	25	151
J Am Acad Dermatol	19	17	21	17	18	15	107
J Invest Dermatol	1	4	2	4	2	0	13

Data kindly provided by Dr. Finola Delamere, Trials Search Co-ordinator of the Cochrane Skin Group.

such information is frequently completely missing from dermatology trial reports (Hoare *et al.*, 2000). The same is true of the description of procedures for blinding those who assess study outcomes, and whether all those randomized were included in the final analysis (intention-to-treat analysis). Just as you would not buy a car without seeing its service-history documentation, we will not buy your trial unless the report includes vital information on how the study was done. Studies that try to improve RCT methodology are of interest as well. Studies that are not strictly RCTs but that form part of clinical trials with unique physiologically based therapies, such as the decrease of skin capillary globotriaosylceramide during treatment with recombinant α-galactosidase A, are always of interest to our readers (Thurberg *et al.*, 2004).

As the *JID* announced last year (Williams and Stern, 2005), it has now also adopted the International Committee of Medical Journal Editors policy for all of its trials to have been registered in an approved publicly accessible clinical-trials register such as the National Institutes of Health register (www.clinicaltrials.gov), the Current Controlled Trials register (http://www.controlled-trials.com/), or the Cochrane Skin Group register, which is unique to dermatology trials (http://www.nottingham.ac.uk/ongoingskintrials/). All trials that started enrolling participants after 1 July 2005 must have been registered before that date in order to be considered for publication in the *JID*. Trials that started enrollment before 1 July 2005 must have been registered before 13 September 2005 in order to be considered for publication (De Angelis *et al.*, 2004). This requirement is an attempt to crack down on the distorting effects of publication bias. Selective reporting distorts the true effects of medical interventions, leading to wastage of doctors' and patients' time and public money and possibly to serious harm (Chalmers, 2004).

It may sound a little odd for us to demand such requirements at a time when we are encouraging new trial submissions, but these are the standards by which the *JID* will work, and our standards are high. Trial reports accepted by the *JID* are assured of widespread and effective dissemination in the highest-impact-factor dermatology specialist journal, and readers will have some reassurance that those published meet minimum quality standards. Let the trials begin.

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SUPPLEMENTARY MATERIAL

Supplementary Article S1. DM Pillsbury *et al.*, "Experimental controls in clinical dermatologic investigation," *J Invest Dermatol* 14:359–71, 1950.

Supplementary Article S2. H Blank, "Clinical trials, a scientific discipline," *J Invest Dermatol* 37:235–40, 1961.

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